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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,174	01/25/2002	Robert E. Briggs	000295.00014	9144

22907 7590 08/10/2004

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EXAMINER	
GRASER, JENNIFER E	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,174	BRIGGS ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-41,66,80-88,91,92 and 95-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *36-41 and 66* is/are allowed.

6)☒ Claim(s) *80-88,91,92 and 95-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/5/02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/24/04 has been entered.

Response to Amendment

2. The Declaration of Robert E.Briggs under 37 CFR 1.132 filed 3/22/04, the amendment to the claims and Applicants' arguments are sufficient to overcome the rejection of 112, 1st enablement rejection.

The terminal disclaimer filed on 3/22/04 has been reviewed and is accepted. The terminal disclaimer has been recorded. Accordingly, the former Obviousness-type Double Patenting (ODP) rejection over US Patent No. 6,495,145 has been obviated. Additionally, Serial No. 09/736,169 was abandoned so the former ODP rejection has been rendered moot.

Specification

3. The current status of all nonprovisional parent applications referenced in the priority data on the first page/line of the specification should be updated, e.g., 09/255,331 has gone abandoned. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 81-88, 91, 92 and 95-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 81, 91 and 95 are vague and confusing due to the wording in lines 3-11 of the claims, e.g., "comprising/comprises at least *two sources of a form of a leukotoxin molecule*, wherein *the form* of the leukotoxin molecule is a deletion mutant of about 66 kDa which lacks amino acids 34 to 378 and which induces antibodies which specifically bind to and neutralize biologically active leukotoxin, wherein the first source is a killed P.haemolytica bacterium, wherein a live form of the killed bacterium (a) expresses no biologically active leukotoxin, (b) expresses *the form* of the leukotoxin molecule and (c) contains no non-P.haemolytica DNA, and wherein the second source comprises *the form of the leukotoxin molecule*, whereby immunity is induced." The claim uses the term "form" for two different products. For example, it is used to refer to the mutated leukotoxin, but in it also used to refer to a 'form' of the killed bacterium. The use of the term "form" coupled with the "sources" is also vague and confusing. It is suggested that Applicants amend the term "form" when referring the leukotoxin to the term "mutated", e.g., two sources of a *mutated* leukotoxin molecule, wherein the *mutated* leukotoxin molecule is a...".

Claim 81 is also vague and confusing with respect to the phrase spanning the last two lines of the claim, e.g., and wherein the second source comprises the form of the leukotoxin molecule. The claim fails to recite the source and is use of

the term "form" is confusing. It is unclear whether 'the second source' is intended to be a component of the vaccine as the first source is or if just the mutated leukotoxin obtained from the second source is to be part of the formulation. This part of the claim should be amended to recite "and wherein the second source comprises the mutated leukotoxin molecule and is selected from the group consisting of the purified mutated leukotoxin, a bacterial lysate, a bacterial extract and a culture supernatant." Applicants have argued that the claim is not indefinite even if the second sources are not disclosed in the claim. They further argue that by putting the limitations of claims 102-104 in the independent claims they are unduly narrowing the claim. This has been fully and carefully considered but is not deemed persuasive. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. By reciting two sources and defining only one source, the claim is vague and indefinite. The specification only teaches that the mutated leukotoxin may be in the form of the purified mutated leukotoxin, a bacterial lysate, a bacterial extract and a culture supernatant. The specification does not enable or provide written description for a composition comprising a 'eucaryotic cell engineered to express the recited molecule'. The way "source" is used in the claim is as if it is a vaccine component, not a source. For example, page 4, lines 1-19, recite "Moreover, bacterial lysates, extracts or culture supernatants which contain the

LktA deletion protein can be used in the vaccine formulation". This appears to be what is intended in the instant claims. The claim with the suggested amendment would not limit mutated leukotoxin derived/isolated from a genetically engineered eucaryotic cell because purified proteins (no matter their source) are included in the scope. The specification, however, does not provide written support for the use of a genetically engineered eucaryotic cell as a vaccine component so the argument that the claims are unduly narrowed by the inclusion of the second source is not valid as the source is taught to be a vaccine component. Otherwise, the claim would just include a killed bacterium and a purified mutated leukotoxin obtained from any of these sources which would be even more limiting than the Examiner's suggested changes. The suggested changes actually broaden, not limit the scope of the claim, because isolated protein is not required, e.g., a supernatant or lysate or extract may be used.

Allowable Subject Matter

6. Claims 66 and 36-41 are allowed.

7. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

J Graser 8/5/04

Jennifer Graser
Primary Examiner
Art Unit 1645